

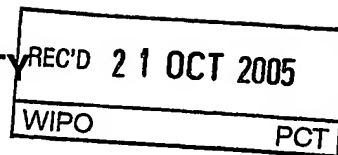
# PATENT COOPERATION TREATY


## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference SCB 881 PCT		<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. PCT/EP2004/012472		International filing date (day/month/year) 04.11.2004	Priority date (day/month/year) 24.11.2003
International Patent Classification (IPC) or national classification and IPC A61K35/78, A61P11/00, A61P31/04, A61P31/10, A61P31/16, A61P31/12, A61P1/02			
Applicant INDENA S.P.A.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  21.09.2005		Date of completion of this report  20.10.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Pilling, S  Telephone No. +49 89 2399-8461	



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/012472

---

**Box No. I Basis of the report**

---

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-7 as originally filed

**Claims, Numbers**

1-15 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/012472

---

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

---

**1. Statement**

Novelty (N)	Yes: Claims	1-15
	No: Claims	
Inventive step (IS)	Yes: Claims	1-15
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-15
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

---

**Box No. VIII Certain observations on the international application**

---

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. The documents cited in the International Search Report (ISR) are consecutively numbered D1 to D11 in the order of their listing. If not indicated otherwise, reference is made to the passages cited in said ISR.
2. As indicated herein below (see Item VIII) the scope of Claims 1 and 15 is wholly indeterminate. However, in order to facilitate processing of the Application it has presently been assumed that the scope of Claim 1 has been clarified to define only the following compositions as indicated by the Applicant, *i.e.*
  - a) compositions comprising anthocyanosides in combination with procyanidins in combination with floroglucinols and;
  - b) compositions comprising anthocyanosides in combination with floroglucinols
3. Based on this assumption, unity of invention (Rule 13.1 PCT and Rule 13.2 PCT) has been accepted.
4. None of the presently available prior art documents appears to clearly disclose compositions (a) or (b) as defined herein above. Thus the subject matter of Claims 1 to 15 is new (Article 33(2) PCT).
5. With regard to inventive step; the presently available prior art documents disclose the following:

each of documents D1 to D4 disclose that anthocyanosides are useful in the treatment of for the treatment of affections of the oral cavity/ upper respiratory tract by virtue of their antiinflammatory (D1)/ antibacterial (D2)/ vasoprotective (D3)/ antiviral (D4) properties;

each of documents D5 to D7 disclose that procyanidins are useful in the treatment of

for the treatment of affections of the oral cavity/ upper respiratory tract by virtue of their antibacterial (D5)/ anticariogenic (D6)/ antiinflammatory (D7) properties;

similarly each of documents D8 to D11 disclose that floroglucinols are useful in the treatment of for the treatment of affections of the oral cavity/ upper respiratory tract by virtue of their antibacterial (D8 to D11) and antimycotic (D9) properties.

6. Thus it appears that each of the components of the presently claimed compositions are known for the treatment of affections of the oral cavity/ upper respiratory tract.
7. The present Applicant has however submitted experimental evidence establishing striking synergistic anti-inflammatory effects for the presently claimed compositions in treating acute bacterial pharyngitis and throat pain. These synergistic anti-inflammatory effects appear to be surprising and could not have been predicted on the basis of any of the presently available prior art documents. Thus the presently claimed subject matter appears to make an inventive contribution to the present art. Thus, the subject matter of Claim 1 to 15 is inventive (Article 33(3) PCT).

**Re Item VIII**

**Certain observations on the international application**

8. The definition of the compositions of Claim 1 is unclear and indeterminate because of the use of the operators "*and/or*" in combination with the operator "*and*". In this regard, the hierarchy of these operators is not defined. Thus it is unclear, for example, whether Claim 1 encompasses (i) compositions containing anthocyanosides alone; and/or (ii) compositions containing anthocyanosides in combination with procyanidins in combination with floroglucinols; and/or (iii) compositions containing procyanidins in combination with floroglucinols. The claims may even encompass further possible combinations. Thus the scope of present Claim 1 is wholly indeterminate (Article 6 PCT). Similar comments apply in respect of Claim 15.
9. The definition in Claim 2 of compositions containing "*1 to 200 mg of anthocyanosides...1 to 200 mg of procyanidins...1 to 200 mg of*

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/EP2004/012472

*floroglucinols..Etc*" is unclear and indeterminate. In this regard, since this claim is not clearly restricted to a unit dose form, *e.g.* a tablet, and/or the total amount of the composition, *e.g.* total volume of 1 ml, is not defined, the definition of ranges of amounts of active agent is meaningless.